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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,816	08/25/2000	Michael R. Yeaman	066742-0026	6324
41552 7590 03/23/2009 MCDERMOTT, WILL & EMERY 11682 EL CAMINO REAL SUITE 400 SAN DIEGO, CA 92130-2047				
EXAMINER				
KAM, CHIH MIN				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
03/23/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/648,816

Applicant(s)

YEAMAN ET AL.

Examiner

CHIH-MIN KAM

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67-69, 76, 79 and 84 is/are rejected.
- 7) ☒ Claim(s) 70-75, 77, 78, 80-83 and 85 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of the Claims

1. Claims 67-85 are pending.

Applicants' amendment filed on January 23, 2009 is acknowledged. Applicants' response has been fully considered. Claim 86 has been cancelled. Therefore, claims 67-85 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claim 86 under 35 U.S.C. 112, second paragraph is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 5 in the amendment filed January 23, 2009.

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 67-69, 76 and 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent 6,743,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69, 76 and 79 in the instant application disclose an isolated antimicrobial peptide

consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acid core sequence that retain antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3, 10 or 13. This is obvious variation in view of claim 1 of the patent which discloses an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10, 13 or 14. Both sets of claims cite an antimicrobial peptide comprising the amino acid sequence of SEQ ID NO:3, 10 or 13. Thus, claims 67-69, 76 and 79 in present application and claim 1 in the patent are obvious variations of an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10 or 13.

4. Claims 67-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U. S. Patent 7,067,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acid core sequence that retain antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3. This is obvious variation in view of claims 1-8 of the patent which disclose a context-activating peptide comprising the amino acid sequence of SEQ ID NO:1, 2, 3 or 4, which contains the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys, and the specification indicates SEQ ID NO:1, 2, 3, or 4 has less anti-microbial activity than the anti-microbial peptide, RP-1 (column 4, line 50-column 5, line 56). Both sets of claims cite an antimicrobial peptide comprising the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys. Thus, claims 67-69 in present

application and claims 1-8 in the patent are obvious variations of an antimicrobial peptide comprising the amino acid core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys.

Response to Arguments

Applicants request that the rejection be held in abeyance until there is an indication of allowable subject matter at which time Applicants will file a Terminal Disclaimer if appropriate. (page 5 of the response).

Applicants' response has been considered. Since a terminal disclaimer has not been filed, the rejection is maintained.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 67-68 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darveau *et al.* (U. S. Patent 5,409,898, published on April 25, 1995).

Darveau *et al.* disclose cationic oligopeptides having at least 8 to 11 amino acids in length and having an amino acid sequence of aa1-Leu-Tyr-Lys-Lys-aa2-aa2-Lys-Lys-Leu-Leu-aa3-aa4-X can form amphipathic alpha helix (column 7, lines 14-20), these cationic oligopeptides include Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly and the like, wherein the helix formed can be either left or right handed and can contain non-protein amino acids such as alpha, alpha-dialkyl amino acids (column 7, lines 46-48; column

10, lines 53-58), which has α helical amphiphilic structure and antibacterial activity (column 12, lines 31-32 and 49-54; column 10, lines 59-64). Although Darveau *et al.* do not provide a specific example for the peptide containing alpha, alpha-dialkylamino acids, the reference does suggest the cationic oligopeptide such as Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly can contain an alpha, alpha-dialkyl amino acid and form amphiphilic helices (column 10, lines 59-64). Thus, at the time of invention was made, it would have been obvious to one of ordinary skill in the art that the cationic oligopeptides would contain alpha, alpha-dialkyl amino acids in the position of hydrophobic residues such as Leu, which results in the claimed invention (claims 67-68 and 84).

Response to Arguments

Applicants indicate Species A is a member of a broad genus taught by Darveau *et al.* having the formula aal-Leu-Tyr-Lys-Lys-aa2-aa2-Lys-Lys-Leu-Leu-aa3-aa4-X (col. 7, lines 16-25, hereinafter genus A), and there is no motivation to cherry pick species A out of the first broad genus among the myriad of disclosed species. Even assuming that species A were chosen, there is a further bridge to gap. The Examiner has used the passage cited at column 10, lines 53-58 to create a subgenus (generated from species A) that allegedly overlaps with the genus of claim 67. First, species A does not fall within the genus of claim 67, and the subgenus created from species A does not represent a reasonably finite set of compounds to suggest the necessary changes to arrive at those species that may overlap with claim 67. Moreover, there is no motivation in Darveau *et al.* to change the particular amino acid residues at positions 6 and/or 7 in the 18 amino acid sequence of species A. In the context of column 10, lines 55-58, the only apparent portions of species A for which there is a suggestion to exchange the naturally

occurring amino acids for the non-protein amino acids are the alpha helical regions. The only region specifically defined as alpha helical in the genus at col. 7, lines 16-25 is portion X, which is a five amino acid sequence being alpha helical in nature, and having the general sequence of aa5-Lys-Lys-aa6-Gly. This does not correspond to positions 6 and/or 7, nor does Darveau indicate that this portion of the peptide is an alpha helical region. Therefore there is no motivation to make the changes in species A, at positions 6 and 7 as suggested by the Examiner, to arrive at theoretical species that overlap with the genus of claim 67. Thus, claim 67 along with claims 68-85 should be patentable over Darveau *et al.*, and the rejection should be withdrawn (pages 5-7 of the response).

Applicants' response has been fully considered, however, the arguments are not found persuasive because of the following reasons. First, claim 67 recites the phrase "modified amino acids of the amino acids in said 7 amino acid core that retains antimicrobial activity", thus the genus of claim 67 encompasses any antimicrobial peptide having a length of 13 to 74 amino acids with a modified amino acid in any amino acid residue of the 7 amino acid core sequence. Thus, the modified amino acid can be not only in 6 or 7 position, but other positions of the core sequence. Second, species A (Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly) was specifically taught by Darveau *et al.* (column 7, lines 47-48), and other species such as SEQ ID NOs: 6, 7, 8 and 10 (column 7, lines 29-39) also contain the sequence of Ala-Leu-Tyr-Lys-Lys-Leu-Leu in the genus of aal-Leu-Tyr-Lys-Lys-aa2-aa2-Lys-Lys-Leu-Leu-aa3-aa4-X, thus, it is obvious to one of ordinary skill in the art to pick up either species A or SEQ ID NOs: 6, 7, 8 or 10 for modification. Furthermore, Darveau *et al.* teach cationic oligopeptides having at least 8 to 11 amino acids in length and having an amino acid sequence of

aa1-Leu-Tyr-Lys-Lys-aa2-Lys-Lys-Leu-Leu-aa3-aa4-X can form amphipathic alpha helix (column 7, lines 14-20), which means that any region of the cationic oligopeptide containing hydrophobic amino acids (e.g., Leu or Try) and hydrophilic amino acids (e.g., Lys) can form alpha helix with the hydrophobic side chains are oriented on one face of the alpha helix and with hydrophilic side chains are oriented on the other face of the alpha helix (See Jaynes et al., U. S. Patent 5,561,107, column 2, lines 26-41). Thus, Darveau *et al.* teach alpha, alpha-dialkyl amino acids can be in not only X region in the formula, but also in other alpha helix regions such as any position (e.g., position 6 or 7) of the Ala-Leu-Tyr-Lys-Lys-Leu-Leu, which results in the claimed antimicrobial peptide having a length of 18 amino acids with a modified amino acid in the 7 amino acid core sequence. Therefore, the rejection is maintained.

Claim Objections

6. Claims 70-75, 77, 78, 80-83 and 85 are objected to because the claims are dependent from a rejected claim.

Conclusion

7. Claims 67-69, 76, 79 and 84 are rejected; and claims 70-75, 77, 78, 80-83 and 85 are objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

March 18, 2009